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Guidance for the Reregistration of Pesticide Products Containing Vendex as the Active Ingredient

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Pesticides

EPA

Guidance for the Reregistration of Pesticide Products Containing Vendex as the Active Ingredient

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This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

FENBUTATIN-OXIDE
(TRADE NAME - VENDEX)
SHAUGHNESSY NO. 104601
MAR 31 1987

AS THE ACTIVE INGREDIENT
CAS NO. 13356-08-6

CASE NUMBER 0245

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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EPA Form 8570-27	Formulator's Exemption Statement

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard. Pesticides have been grouped into use clusters and will be reviewed on the basis of a ranking scheme giving higher priority to (1) pesticides in clusters used on food and feed crops; and (2) pesticides produced in large volumes.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

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[1] The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division (TS-757C), EPA, 401 M St., SW, Washington, D.C. 20460.

1. Submission of data in support of product registration;
2. Modification of product labels;
3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;
4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;
5. Modification of uses or formulation types; or
6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as their products are registered by the Agency.

II. CHEMICAL(S) COVERED BY THIS STANDARD

A. Description of chemical(s)

The following chemical is covered by this Registration Standard:

Common name:	Fenbutatin-oxide
Chemical name:	Bis [tris(2-methyl-2-phenylpropyl)tin] oxide or hexakis (2-methyl-2-phenylpropyl)-distannoxane
CAS Number :	13356-08-6
OPP (Shaughnessy) Numbers:	104601
Empirical Formula:	$C_{60}H_{78}OSn_2$
Trade and other names:	Vendex, Fenbutatin oxyde, SD 14114, Torque, Neostanox, Osadan and Hexakis

Description of physical characteristics of chemical:

Technical Fenbutatin-oxide

Color: White
Odor: Odorless
Physical State: Crystalline solid

Melting point: 145°C
Solubility: Insoluble in water and slightly soluble in aromatic sovents
Molecular Weight: 1053

B. Use Profile

Type of Pesticide: Organotin acaricide, refer to Pesticide Index (Appendix III).
Predominant Use(s): Oranges, grapefruit, pears, apples, grapes, almonds, cherries, strawberries and ornamentals
Mode of Activity: It is suspected that fenbutatin-oxide inhibits adenosine triphosphate (ATP) enzymes.

Methods of Application: Foliar application by ground equipment only

Fenbutatin-oxide is the common name for hexakis (2-methyl-2-phenylpropyl) distannoxane and this common name will be used through out this Guidance Document. Fenbutatin-oxide is a non-systemic organotin acaricide that has been marketed in the United States for 12 years and is used to control more than 20 different types of mites on about 17 sites. All fenbutatin-oxide registrations were recently transferred from Shell Chemical to E.I. du Pont de Nemours and Company.

There are 3 registered products with the following formulations:

Technical (97%)
Wettable Powder (50%)
Flowable Concentrate (4 lb/gal)

Fenbutatin-oxide is used on a variety of use sites which include: almonds, apple, cherry, citrus fruits, eggplant, grapes, papaya, peach, pear, pecan, plum, prune, strawberry, walnut and ornamentals. Recommended application rates range from 0.5 pounds active ingredient (a.i.) per acre to 2.0 pounds a.i. per acre.

III. AGENCY ASSESSMENT

A. SUMMARY

The Agency has reviewed data submitted to support the registration of fenbutatin-oxide and concluded that numerous data gaps exist for fenbutatin-oxide. However, based on available data the Agency has reached the following conclusions. (A detailed discussion of the points summarized below appears in Section B.)

1. A primary eye irritation study demonstrates that technical fenbutation-oxide is a severe eye irritant and is therefore classified as a Toxicity I chemical based on eye effects only. The Agency believes that the precautionary statements concerning these eye effects presently on fenbutatin-oxide labels are adequate to protect the public.

2. Available data demonstrate that the use of fenbutatin-oxide in citrus groves may present a chronic hazard to nesting and foraging birds and an acute hazard to freshwater and estuarine aquatic organisms. Until the required data are developed and submitted, hazards can be reduced through labeling statements. (Refer to Section IV A for a description of the required data).

The Agency has identified the data it feels is necessary to fully evaluate the human and environmental risks associated with the use of fenbutatin-oxide. These data must be developed in order to maintain registrations of products or to register new products containing fenbutatin-oxide. A summary of these data gaps appears in Figure I. Please note that this is only a summary and complete details can be obtained by referring to the tables in Appendix I.

The Agency has also determined that certain label restrictions and revisions are necessary. Please refer to Section VI.D. for a description of the required labeling revisions.

Figure 1- DATA GAP TABLE

Toxicology

Acute Oral (Rat)
Acute Inhalation (Rat)
90 Day Feeding (Non-rodent)
21 Day Dermal Toxicity
Chronic Toxicity (Non-rodent)
Oncogenicity (Mouse)
Mutagenicity
General Metabolism Testing
2-Generation Reproduction

Environmental Fate

Leaching
Hydrolysis
Photodegradation (In water)
Photodegradation (On soil)
Aerobic and Anaerobic Soil Metabolism Studies
Volatility (Lab)
Soil Dissipation
Rotational Crops (Confined)
Accumulation in Fish

Re-entry

Foliar Dissipation

Product Chemistry/Residue Chemistry

Product Chemistry
Animal Metabolism
Storage Stability
Residue Studies

Ecological Effects

Avian Subacute Dietary Toxicity
Avian Reproduction
Freshwater Fish Toxicity
Acute Toxicity to Freshwater Invertebrates and Marine Organisms
Fish Early Life Stage and Aquatic Invertebrate Life Cycle
Aquatic Organism Accumulation Testing
Simulated or Actual Field Testing for Aquatic Organisms

B. PRELIMINARY RISK ASSESSMENT

The Agency has reviewed fenbutatin-oxide data in the areas of acute toxicity, chronic toxicity, oncogenicity, reproductive effects, mutagenicity, environmental fate and exposure, and ecological effects. Numerous data gaps exist. The following assessment is based on available data and is subject to change when the results of the required studies are available for Agency review. (Refer to Section C for a detailed discussion of other science findings not covered in the Preliminary Risk Assessment Section).

1. Toxicology

a. Eye Irritation

Six male Albino rabbits were administered 100 mg of undiluted technical fenbutatin-oxide in the conjuctival sac of the treated eye. All animals showed damage to the cornea, iris and conjunctiva up to 14 days post treatment. Based upon this primary eye irritation study, technical fenbutatin-oxide is characterized as a severe eye irritant and is classified as a Toxicity Category I chemical because of eye effects.

2. Ecological Effects

Birds

An acute oral avian toxicity study indicates that fenbutatin-oxide, when administered orally in a single dose, is practically nontoxic to birds. The LD_{50} value for Bobwhite Quail is 2510 mg/kg.

A subacute dietary toxicity study on Mallard ducks likewise supports a finding indicating that fenbutatin-oxide is nontoxic to birds. The LC_{50} value for Mallard ducks is greater than 5620 parts per million (ppm). (A subacute dietary toxicity study using Bobwhite Quail must be repeated because the administered dose was not sufficient to calculate a reliable LC_{50} value).

Aquatic Organisms

Preliminary freshwater invertebrate acute toxicity data indicate that fenbutatin-oxide is highly toxic to freshwater invertebrates. This study was classified as supplemental data and must be repeated because the test water was not properly characterized and only 3 dose levels, rather than 5 levels, were used. The tentative LD_{50} value for *Daphnia magnia* is 0.04 ppm.

Acute toxicity data on Rainbow trout and Bluegill sunfish indicate that fenbutatin-oxide is highly toxic to freshwater fish. The LC_{50} value for Rainbow trout is 0.0017 ppm. The LC_{50} value for Bluegill sunfish is 0.0048 ppm.

Wildlife Exposure and Hazard

The highest application rates for fenbutatin-oxide are applied to citrus crops in Florida at a rate of 2 lbs active ingredient per acre. Use directions allow for up to 4 total applications to citrus with each application being 2 to 3 weeks apart.

The Agency is carefully evaluating fenbutatin-oxide use on citrus for the following reasons:

a. Repetitive applications could result in an accumulation of parent fenbutatin-oxide and metabolites that, because of the persistent nature of the pesticide, may present a chronic hazard to birds foraging in soils and nesting in citrus groves.

b. Although run-off does not appear to present a risk to aquatic species, spray drift resulting from application of fenbutatin-oxide to citrus groves may pose an acute toxicity hazard to freshwater and estuarine species.

The Agency is requiring avian reproduction, acute aquatic and avian toxicity testing, chronic toxicity testing as well as aquatic field monitoring studies be conducted before the wildlife risk assessment can be completed. (Refer to Appendix I for a complete listing of required data).

C. OTHER SCIENCE FINDINGS

1. Acute and Subchronic Toxicity

Available dermal toxicity data demonstrate that fenbutatin-oxide exhibits low toxicity to mammals by dermal route of exposure. The acute dermal toxicity to rabbits is greater than 2,000 mg/kg.

Data are sufficient to indicate that fenbutatin-oxide is not a dermal sensitizer. Primary dermal irritation data demonstrate that fenbutatin-oxide is a mild skin irritant.

No valid acute oral toxicity, acute inhalation, 90 day feeding (non-rodent) or subchronic dermal toxicity studies are available. These data are required.

2. Chronic Toxicity

Rat

An acceptable 2 year rat feeding study, where 72 male and 72 female Carworth rats were administered fenbutatin-oxide in dietary doses of 50, 100, 300 and 600 ppm for 104 weeks, demonstrated that fenbutatin-oxide was not oncogenic under test conditions. One hundred forty-four animals of each sex were used as controls. A systemic No Observed Effect Level (NOEL) of 100 ppm (or 5 mg/kg) was established based on decreased leucocytes in female rats and reduced body weight in both sexes receiving dosages greater than 300 ppm.

Non-rodent

A 2 year dog feeding study was reviewed and found to be supplemental because of reporting deficiencies. The study may be upgraded when the required information listed in Appendix I is submitted and reviewed.

In this study, male and female dogs (4 animals per sex per dose) were administered fenbutatin-oxide in gelatin capsules containing 2.5, 5, 15, 30 and 60 mg/kg. The control group consisted of 8 animals per sex.

These preliminary data indicate that the NOEL is considered to be 5 mg/kg/day with a lowest effect level of 15 mg/kg/day based on clinical observations of vomiting and diarrhea.

3. Oncogenicity

Rat

The rat chronic/oncogenicity study previously described in Section C2 adequately assesses the oncogenicity of fenbutatin-oxide. No oncogenic effects were demonstrated at doses up to 600 ppm, the highest level tested).

Mouse

An 18 month feeding/oncogenicity study was reviewed and found to be supplemental because of reporting deficiencies. The study may be upgraded when the required information listed in Appendix I is submitted and reviewed. Sixty male and sixty female Carworth mice were fed diets containing 5, 100, 300, 600 ppm of fenbutatin-oxide. A control group of 120 male and 120 female mice received an untreated diet.

Preliminary data indicate that the NOEL is 100 ppm based on decreased body weight. No oncogenic effects were reported at the highest dose tested.

4. Reproductive and Teratogenic Effects

Reproduction

There are no valid reproduction studies available to assess reproductive effects from fenbutatin-oxide exposure. This study is required.

Teratology

Rat

An acceptable rat teratology study demonstrates that fenbutatin-oxide is not teratogenic in the rat. The NOEL for this study is 60 mg/kg, the highest dose tested.

One hundred thirty six female Wistar rats were administered fenbutatin-oxide by gavage at doses of 15, 30 or 60 mg/kg from 6 through 15 days of pregnancy. Fifteen female rats were administered aspirin which served as the positive control.

Rabbit

A rabbit teratology study was reviewed and found to be acceptable. Female New Zealand White rabbits were administered fenbutatin-oxide in gelatin capsules at doses of 1, 5, and 10 mg/kg on days 6-18 of gestation. Thalidomide was given as the positive control. The NOEL for this study as 5 mg/kg.

5. Mutagenicity and Metabolism

There are no valid mutagenicity or metabolism studies available. These studies must be conducted and submitted to the Agency.

6. Environmental Fate

The available data are insufficient to fully assess the environmental fate of fenbutatin-oxide. Refer to Appendix I for a listing of required data.

D. Tolerance Assessment

1. Tolerances issued

Tolerances have been established for residues of fenbutatin-oxide in a variety of raw agricultural commodities including meat, fat and meat by products (refer to 40 CFR 180.362 for listing of tolerances), and in processed food (21 CRF 193.236) and feed (21 CFR 561.255).

	Tolerance (ppm)			(MRL)
Commodity	U.S.	Canadian	Mexican	Codex
Almonds	0.5	-	-	-
Almonds, hulls	80.0	-	-	-
Apples	15.0	3.0	-	5.0
Cattle,fat	0.5	-	-	-
Cattle,meat by product	0.5	-	-	-
Cattle,meat	0.5	-	-	0.02
Cherries,sour	6.0	-	-	5.0
Cherries,sweet	6.0	-	-	5.0
Citrus fruits	2.0	2.0	-	5.0
Cucumber	4.0	0.5	-	1.0
Eggplant	6.0	-	-	1.0
Eggs	0.1	-	-	-
Goats,fat	0.5	-	-	-
Goats,meat by product	0.5	-	-	-
Goats,meat	0.5	-	-	-
Grapes	5.0	-	-	5.0
Hogs,fat	0.5	-	-	-
Hogs,meat by products	0.5	-	-	-
Hogs,meat	0.5	-	-	-
Horses,fat	0.5	-	-	-
Horses,meat by product	0.5	-	-	-
Horses,meat	0.5	-	-	-
milk fat	0.1	-	-	-
Papayas	2.0	-	-	-
Pecans	0.5	-	-	-
Peaches	10.0	-	-	7.0
Pears	15.0			
Plums	4.0	-	-	3.0
Poultry,fat	0.1	-	-	-
Poultry, meat by products	0.1	-	-	-
Poultry,meat	0.1	-	-	-
Prunes	4.0	-	-	-
Sheep,fat	0.5	-	-	-
Sheep, meat by products	0.5	-	-	-
Sheep,meat	0.5	-	-	-
Strawberries	10.0	-	-	-
Walnuts	0.5	-	-	-
Apple pomace,dried	20.0	-	-	-
Citrus pulp,dried	7.0	-	-	-
Grape pomace,dried	100	-	-	-
Raisin waste	20.0	-	-	-
Prunes,dried	8.0	-	-	-
Raisins	20.0	-	-	-

2. Residue Data

The residue data reviewed in support of these fenbutatin-oxide tolerances are:

a. Data on the nature of the residue in both plants and animals, including identification of major metabolites and degradates of fenbutatin-oxide.

The nature of the residue of fenbutatin-oxide in animals is not adequately understood because: (1) insufficient residue levels were present in milk and meat of dairy cows for characterization, (2) residues in laying hens were not properly characterized due to problems with analytical methodology, and (3) no material balance information was provided for residues recovered from laying hens. The limited data do show that up to 82% of fenbutatin-oxide residues were recovered from the feces of dairy cattle that were fed diets containing radiolabeled fenbutatin-oxide. No detectable fenbutatin-oxide residues or metabolites were detected in milk, fat or muscle of cattle and less than one percent of the total administered dose occured in the lungs, liver, kidneys and urine combined. Characterization of residues in the liver and kidney revealed the presence of fenbutatin-oxide per se, dihydroxy-bis(2-methyl-2-phenylpropyl) stannane and inorganic tin.

A fenbutatin-oxide hen feeding study indicated that fenbutatin-oxide residues were found in egg yolks, liver and kidney. Due to problems with analytical methodology and residue recovery, however, a new study must be conducted and submitted.

The metabolism of fenbutatin-oxide in plants is adequately understood and no additional data are required. Available data demonstrate that fenbutatin-oxide residues (fenbutatin-oxide, dihydroxy-bis-(2-methyl-2-phenylpropyl) stannane, 2-methyl-2phenylpropyl stannonic acid and other organic and inorganic compounds) were detected in treated leaves and fruit of apples and oranges.

Tolerances of fenbutatin-oxide are currently expressed as the combined residues of hexikis (2-methyl-2-phenylpropyl)-distannoxane and its organotin metabolites. Upon receipt of the required animal data, the tolerance expression will be re-evaluated.

b. Adequate gas-liquid chromatographic (GLC) methods, utilizing either a tin-specific flame photometric detector or mass selective detector are available for collection of data pertaining to residues of fenbutatin-oxide and its organotin metabolites. A method trial for two procedures is needed for the determination of fenbutatin-oxide and its metabolites. Data for residues of fenbutatin-oxide and its organotin metabolites in or on crop samples must be analyzed using the multiresidue methods published in PAM, Vol. I.

c. Storage stability data demonstrate that the metabolites dihydroxy-bis (2-methyl-2-phenypropyl) stannane and 2-methyl-2-phenylpropyl stannonic acid were stable in frozen chicken tissue and egg samples stored at -10°F for up to four months.

Additional storage stability data are required in order to evaluate the adequacy of numerous established tolerances.

d. Data on the magnitude and levels of residues of fenbutatin-oxide are sufficient to determine the adequacy of the established tolerances for residues of fenbutatin-oxide in or on almonds, almond hulls, apples, cherries (sweet and sour), citrus fruits, eggplant, grapes, papayas, peaches, pears, pecans, plums, raspberries, strawberries and walnuts. There are not sufficient data available to ascertain the adequacy of the established tolerances for residues of fenbutatin-oxide in or on cucumbers. Processing studies are required for apples, citrus fruits, grapes and plums.

Because of the numerous residue chemistry data gaps, the Agency cannot conduct a tolerance reassessment until the required data are received and reviewed.

2. Toxicology.

A 2 year rat feeding study, originally used to support the previously established tolerances for residues of fenbutatin-oxide, has been re-evaluated and found to be acceptable to continue supporting the existing tolerances. Based upon a No Observed Effect Level (NOEL) of 100 ppm for systemic effects, and using a 100 fold safety factor, the Acceptable Daily Intake (ADI) was calculated to be 0.05 mg/kg/day. (An ADI rather than a PADI, or provisional ADI, was used because available data, deemed to be supplemental due to reporting deficiencies, demonstrate that the no effect level of 100 ppm is not likely to change upon resubmission of required data). The MPI (Maximum Permissible Intake), for a 60 kg individual was found to be 3.0 mg/kg/day. The Theoretical Maximum Residue Contribution (TMRC) for all published tolerances was calculated to be 0.0357 mg/kg/day for a 1.5 kg diet. The TMRC utilized 71.4% of the ADI.

Because of the extensive residue chemistry and toxicology data gaps, the Agency cannot conduct a full tolerance reassessment. The tolerances will be reassessed when the required data are received and reviewed.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS AND RATIONALES

Based on a review and evaluation of all available data and other relevant information on fenbutatin-oxide, the Agency has made the following determinations:

1. The Agency is requiring the submission of acute aquatic toxicity data and aquatic field monitoring data on the end use formulations and aquatic life stage data and avian reproduction data on the technical formulation.

Rationale

Based on acute toxicity data, use pattern, and modeling information, the use of fenbutatin-oxide in citrus groves may present a chronic hazard to nesting and foraging birds and an acute hazard to freshwater and estuarine aquatic organisms. Upon receipt of the required data, the Agency will complete the hazard assessment.

2. The Agency is imposing a 24 hour reentry interval and is requiring that protective clothing statements for all fenbutatin-oxide products be revised to include labeling language for early reentry into treated fields. (Refer to Section IV D for specific labeling requirements).

Rationale

As required in PR Notice 83-2, fenbutatin-oxide product labels currently prohibit workers from reentering treated fields without protective clothing unless sprays have dried. However, because of a few California incidence reports and the fact that this chemical is acutely toxic due to adverse eye effects, the Agency is imposing an interim 24 hour reentry interval in an effort to further reduce exposure. It may be noted that both California and Texas have established 24 hour reentry intervals. This interim reentry interval will be retained until the required reentry data are received and evaluated.

Technical fenbutatin-oxide is characterized as a severe eye irritant and is classified as a Toxicity Category I chemical because of eye effects. The Agency is requiring that these statements be modified and upgraded to further protect persons involved in early reentry into treated fields.

3. No significant new food uses* will be granted until the Agency has received sufficient data to evaluate the dietary exposure to fenbutatin-oxide.

Rationale

The Residue Chemistry and Toxicology data bases for fenbutatin-oxide are not sufficient to assess the existing tolerances. Animal metabolism and residue data including processing studies as well as data on various commodities are required. The required toxicology data include: chronic feeding, oncogenicity, 2-generation reproduction, mutagenicity and metabolism testing. (Refer to Appendix I, for a listing of required residue chemistry and toxicology data).

4. The Agency will not require endangered species labeling at this time.

Rationale

Since 1982, cotton, corn, small grains, sorghum, soybeans, rangeland, forest and mosquito larvicide uses have been reviewed under a cluster approach to determine the endangered species impacted by certain pesticide uses. Fenbutatin-oxide, however, is not registered for the above listed uses and therefore, does not fall under this cluster analysis for endangered species.

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* Significant new use us defined in 44 FR 27934, May 11, 1979. In the case of a new food or feed use, the Agency will consider as significant an increase in the Theoretical Maximum Residue Contribution of greater than one percent.

An analysis of pesticides with similar uses to fenbutatin-oxide revealed that a number of endangered species were found to be in jeopardy but based on modeling (exposure concentrations in this model did not exceed the endangered species trigger), use information and available toxicity data, fenbutatin-oxide does not appear to pose a threat to endangered species.

Future analysis of uses that have not been reviewed in the cluster project may necessitate the need for endangered species labeling.

5. The Agency has identified certain data that will receive immediate review when submitted.

Rationale

Certain data are deemed essential to the Agency's assessment of this pesticide and a review of these data may trigger the need for further studies which should be initiated as soon as possible (e.g. tier studies). The following studies have been identified to receive priority review as soon as they are received by the Agency:

158.140 Environemntal Fate

132-1 Foliar Dissipation (Re-entry)

158.145 Ecological Effects

72-4 Fish Early Life Stage and Aquatic Invertebrate Life Cycle
72-3 Acute Toxicity- Aquatic Estuarine and Marine Organism
72-7 Field Testing for Aquatic Organism

6. The tolerance regulation must be revised to separately list fenbutatin-oxide and its organotin metabolites.

Rationale

At present all established tolerances are expressed as the combined residues of the parent compound and its organotin metabolites calculated as the parent compound. The Agency is requiring that the fenbutatin-oxide organotin metabolites be listed separately in the tolerance regulation so that established tolerances can be made compatible with the Maximum Residue Limits (MRL's) established by the Codex Alimentarius Commission, an organization set up in the United Nations designed to facilitate international trade.

7. While data gaps are being filled, currently registered manufacturing use products (MPs) and end use products (EPs) containing fenbutatin-oxide as the sole active ingredient may be sold, distributed, formulated and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale

Under FIFRA, the Agency does not normally cancel or withold registration simply because data are missing or inadequate (see FIFRA sec. 3(c)(2)(B) and 3(c)(7). Issuance of this standard provides a mechanism for identifying data needs. These data will be reviewed and evaluted, after which the Agency will determine if additional regulatory changes are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain fenbutatin-oxide as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain fenbutatin-oxide as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1%.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing fenbutatin-oxide provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products only for the commodities listed in the Index in Appendix III. The use Index lists all registered uses, as well as approved maximum application rates and frequencies.

D. REQUIRED LABELING

All manufacturing-use products (and end-use products, if covered by Standard) must bear appropriate labeling as specified in 40 CFR 162.10. Appendix II contains information on label requirements.

No pesticide product containing fenbutatin-oxide may be released for shipment by the registrant after 12 months from receipt of this document unless the product bears an amended label which complies with the requirements of this Standard.

No pesticide product containing fenbutatin-oxide may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to be delivered by any person after 24 months from receipt of this document unless the product bears an amended label which complies with the requirements of this Standard.

In addition to the above, the following information must appear on the labeling:

1. Ingredient Statement

The ingredient statement for all fenbutatin-oxide products must list the active ingredient as:

ACTIVE INGREDIENTS:

Fenbutatin-oxide (Hexakis(2-methyl-2-phenylpropyl) distannoxane. . . . ______%

INERT INGREDIENTS: . . . . ______%

2. All products must have a statement of practical treatment and in the following format:

If in eyes:	Immediately flush eyes with plenty of water. Call a physician.
If inhaled:	Remove from exposure and have patient lie down and keep quiet. If patient is not breathing, start artificial respiration immediately. Never give anything to an unconscious person.
If on skin:	Wash skin with plenty of soap and water.
If swallowed:	Do not induce vomiting. Call a physician.

Manufacturing Use Product Labeling

1. Use Pattern Statements

All manufacturing use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites, which are listed in the Index in Appendix III. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in Table A for that use pattern.

2. Precautionary Statements

Labels for manufacturing-use and end-use products must bear statements reflecting the compound's acute human toxicity. Fenbutatin-oxide is classified in Toxicology Category I on the basis of eye irritation only. All the precautionary labeling language that is currently on fenbutatin-oxide labels is to be retained.

3. Environmental Hazards Statement

The following revised environmental hazard statement must appear on all manufacturing use product labels:

> "This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewer treatment plant authority. For quidance contact your State Water Board or Regional office of the EPA."

End Use Product Labeling

a. Environmental Hazards Statement:

> "This product is toxic to fish. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes."

b. Reentry Statement:

> "Do not enter treated fields within 24 hours of application unless long pants and long-sleeved shirt (or coveralls); chemical resistant gloves; shoes; and goggles or a face shield are worn."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

The data requirements listed in Table A.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

a. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

b. If eligible for the formulator's exemption, the data requirements listed in Table C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients. (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from (or are not specified in) either EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing and await EPA approval, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

F. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made before the deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. Time extensions may be considered when joint data development is planned, or when the Agency must approve a new or modified protocol before the study can be begun.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

G. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing FENBUTATIN-OXIDE as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing FENBUTATIN-OXIDE in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing FENBUTATIN-OXIDE as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

E. Addresses

The required information must be submitted to the following address:

Dennis Edwards (PM-12)
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

F. Intrastate Products containing FENBUTATIN-OXIDE either as sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

G. Address

The required information for intrastate products only must be submitted to the following address:

Stuart McArthur
Registration Support and Emergency Response Branch (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data? 1/	Bibliographic Citation	Must Additional Data be Submitted? 2/	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	No	-	Yes 2/	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	No	-	Yes 2/	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	All	No	-	Yes 2/	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	No	-	Yes 2/	6 Months
63-3 - Physical State	TGAI	All	No	-	Yes 2/	6 Months
63-4 - Odor	TGAI	All	No	-	Yes 2/	6 Months
63-5 - Melting Point	TGAI	All	No	-	Yes 2/	6 Months
63-6 - Boiling Point	TGAI	All	No	-	Yes 2/	6 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data? 1/	Bibliographic Citation	Must Additional Data be Submitted? 2/	Time Frame for Submission
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	No	-	Yes 2/	6 Months
63-8 - Solubility	TGAI or PAI	All	No	-	Yes 2/	6 Months
63-9 - Vapor Pressure	PAI	All	No	-	Yes 2/	6 Months
63-10 - Dissociation constant	PAI	All	No	-	Yes 2/	6 Months
63-11 - Octanol/water partition coefficient	PAI	All	No	-	Yes 2/	6 Months
63-12 - pH	TGAI	All	No	-	Yes 2/	6 Months
63-13 - Storage Stability	TGAI	All	No	-	Yes 2/	15 Months

1/ Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

2/ Generic data are required for the following technical formulation : EPA REG. NO. 201-367.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
158.125 Residue Chemistry					
171-4 Nature of the residue (Metabolism)					
- Plants	PAIRA	Yes	00113018	No1/	
- Livestock	PAIRA	Partially	00113018 00113020 00113078 00113029	Yes2/	18 Months
171-4 Residue analytical methods					
- Plant and Animal Residues	TGAI & Metabolites	Partially	00026038 00030349 00045869 00045870 00069881 00070506 00077245 00093721 00105161 00105203 00105204 00109280	Yes3/	15 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

Data Requirement		Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
158.125	Residue Chemistry					
171-4	Residue analytical method (Continued)					
	- Plant and Animal Residues			00112902 00113018 00113063 00113078 00143694 00145444 00146038 00148257 00148733 00130837		
171-4	Storage stability data	TEP & Metabolites	Partially	00113063 00113078 00146038	Yes 4/5/	15 Months
171-4	Magnitude of the Residue					
	- Crop field trials					
	- Fruiting Vegetables 6/ (except Cucurbits) Group					
	o Eggplant	TEP	Yes	00130837	No	
	- Cucurbit Vegetables 7/8/ Group					

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

ata Requirement		Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
171-4	Magnitude of the Residue					
	- Crop field trials (continued)					
	o Cucumbers	TEP	Partially	00146038	Yes[9/]	18 Months
	- Citrus Fruits Group	TEP	Partially	00030349 00093721 00105204 00113018	Yes[10/]	24 Months
	- Pome Fruits Group 11/					
	o Apples	TEP	Partially	00030349 00105204 00113018	Yes[12/]	24 Months
	o Pears	TEP	Yes	00030349 00093721 00105204 00113018	No	
	- Stone Fruits 13/ Group					
	o Cherries (sweet and sour)	TEP	Yes	00026038 00112902	No	
	o Peaches	TEP	Yes	00026038 00148257	No	
	o Plums (fresh prunes)	TEP	Partially	00026038 00112902	Yes[14/]	24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

Data Requirement		Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
171-4	Magnitude of the Residue - Crop field trials (continued)					
	- Small Fruits and Berries Group [15/]					
	o Grapes	TEP	Partially	00077245 00105203 00113078	Yes[16/]	24 Months
	o Raspberries	TEP	Yes	00145444	No	
	o Strawberries	TEP	Yes	00069881 00071183 00148257 00148733	No	
	- Tree Nuts Group [11/]					
	o Almonds	TEP	Yes	00109280 00113078	No	
	o Pecans	TEP	Yes	00105161 00109280 00113063	No	
	o Walnuts	TEP	Yes	00105161 00109280	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

Data Requirement		Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
171-4	Magnitude of the Residue - Crop field trials (continued)					
	- Miscellaneous Commodities					
	o Avocados 17/					
	o Papayas	EP	Yes	00045869	No	
	- Meat/milk/poultry/eggs		Partially	00113078	reserved 18/	

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

§158.125 Residue Chemistry - Continued

1/ The present tolerance regulation should be modified to specifically name fenbutatin-oxide and its metabolites dihydroxybis(2-methyl-2-phenyl-propyl) stannane, 2-methyl-2-phenyl-propyl stannonic acid and possibly inorganic tin.

2/ Metabolism studies in ruminants and poultry fed technical grade [^{119}Sn]fenbutatin-oxide, which must be complety characterized (including impurities) and representative of the technical fenbutatin-oxide currently used in commercial formulations. Animals must by dosed for at least three days with concentrations in the diet which will result in sufficient residues in tissues, milk, and eggs for characterization. Milk and eggs must be collected for analysis twice daily, and animals must be sacrificed within 24 hours of the final dosing. The distribution and identity of ^{119}Sn-residues must be determined and quantified in the milk, muscle, fat, kidney, and liver of ruminants, and in the eggs, muscle, fat, kidneys, and liver of poultry. At such time as these studies are completed and submitted the present tolerance regulation should be modified to specifically name fenbutatin-oxide and any metabolites of concern.

3/ Residues of fenbutatin-oxide and its organotin metabolites in or on crop samples must be subjected to analysis by the multiresidue methods published in PAM, Vol. I. Protocols for methods I, II, III, and IV are available from the National Technical Information Service under Order No. PB86 203734/AS. Also, since the present tolerance regulation is to be modified to specifically name fenbutatin-oxide and metabolites of concern, if Toxicology Branch deems that each metabolite must be quantitated separately, then methodology for plant and animal commodities including validation data and a method trial will be needed.

4/ The storage intervals and conditions of storage of all samples used to evaluate all established tolerances for residues of fenbutatin-oxide and its organotin metabolites must be submitted. These data must be accompanied by data depicting the percent decline in residues at the time and under the conditions specified for each test. On receipt of these data, the adequacy of the aforementioned tolerances will be reevaluated.

5/ All residue data requested in this Standard must be accompanied by data on the conditions and intervals of sample storage. Fortification recovery data must also be included which depict the stability of residues of fenbutatin-oxide and its organotin metabolites in appropriate sample substances under the conditions and for the time intervals used in the tests.

6/ Use directions must be proposed, and appropriate supporting residue data submitted for the representative group members tomatoes and peppers.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

§158.125 Residue Chemistry - Continued

7/ Use directions must be proposed, and appropriate supporting residue data must be submitted for melons (cantaloupe or muskmelon) and summer squash.

8/ Appropriate supporting residue data collected using an adequate analytical method must be submitted for cucumbers.

9/ The registrant must propose use directions for fenbutatin-oxide on cucumbers and provide appropriate supporting residue data (collected using an adequate analytical method). Residue data must reflect the combined residues of fenbutatin-oxide and its organotin metabolites calculated as fenbutatin-oxide in or on cucumbers.

10/ Data reflecting the combined residues of fenbutatin-oxide and its organotin metabolites (calculated as fenbutatin-oxide) in dried citrus pulp, wet pulp, molasses, juice, and oil processed from citrus fruit bearing weathered residues. Exaggerated rates may be necessary to achieve these residues in or on the fruits. If residues are found to concentrate in dried citrus pulp the established food additive tolerance may need to be amended. If residues are found to concentrate in wet citrus pulp, molasses, juice, or oil, appropriate food/feed additive tolerances must be proposed.

11/ The available data are sufficient to determine that a crop group tolerance is appropriate at the present time.

12/ Data depicting the combined residues of fenbutatin-oxide and its organotin metabolites (calculated as fenbutatin-oxide) in dried apple pomace and juice processed from apples bearing measurable weathered residues. Exaggerated rates may be necessary to achieve these residues in or on the fruits. If residues are found to concentrate in dried apple pomace the established food additive tolerance may need to be amended. If residues are found to concentrate in juice, an appropriate food additive tolerance must be proposed.

13/ Conclusions may not be made at the present time because available data in support of the proposed crop group tolerance are currently under review.

14/ Tests reflecting the combined residues of fenbutatin-oxide and its organotin metabolites (calculated as fenbutatin-oxide in prunes processed from plums (fresh prunes) bearing measurable weathered residues. Exaggerated rates may be necessary to achieve these residues in or on the fruits. If residues are found to concentrate, then the established food additive tolerance may need to be amended.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

§158.125 Residue Chemistry - Continued

15/ Proposed use directions must be submitted along with appropriate supporting residue data for blackberry (Rubus spp.), blueberry, and cranberry.

16/ Data depicting the combined residues of fenbutatin-oxide and its organotin metabolites (calculated as fenbutatin-oxide in raisins, raisin waste, dried grape pomace, and grape juice processed from grapes bearing measurable weathered residues. If residues are found to concentrate in raisins, raisin waste, or dried grape pomace, the established food/feed additive tolerances may need to be amended. If residues concentrate in juice, an appropriate food additive tolerance must be proposed.

17/ Conclusions may not be made at the present time because available data in support of the proposed tolerance for the combined residues of fenbutatin-oxide and its organotin metabolites calculated as fenbutatin-oxide in or on avocados are currently under review.

18/ On receipt of the data requested in 2/ above, the appropriate nature of tolerances for residues in animal products will be determined and, with consideration for any newly found metabolites of toxicological concern, the adequacy of the available data regarding the magnitude of residues in fat, meat, and meat by-products will be determined.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B,F	No	-	Yes	9 Months
Photodegradation						
161-2 - In water	TGAI or PAIRA	A,B	No	-	Yes	9 Months
161-3 - On soil	TGAI or PAIRA	A	No	-	Yes	9 Months
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,F	No	-	Yes	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No	-	Yes	27 Months
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,F	Partial	00071228	Yes/1	12 Months
163-2 - Volatility (Lab)	TEP	A,F	No	-	Yes	12 Months
163-3 - Volatility (Field)	TEP	A,F	No	-	Yes/2	15 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
158.130 Environmental Fate - Continued						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B	No	-	Yes	27 Months
164-5 - Soil, Long-term	TEP	A	No	-	Reserved/3	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	No	-	Yes	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No	-	Reserved/4	
165-4 - In Fish	TGAI or PAIRA	A,B	No	-	Yes	12 Months
165-5 - In Aquatic Non-Target Organisms	TEP	N/A	No	-	Reserved/5	

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

§158.130 Environmental Fate - Continued

1/ A study is required on the mobility of aged fenbutatin-oxide residues in sandy loam soil.
2/ Study reserved pending receipt and review of required laboratory volatility data.
3/ Study reserved pending receipt and review of required field dissipation data.
4/ Study reserved pending receipt and review of required confined crop rotation study. No interim crop rotation label restriction is being imposed because of the data gap. Rotation crop uptake data are being required in this registration standard. When acceptable uptake data are received, the Agency will assess crop residue uptake and apply appropriate regulatory safeguards.
5/ Study reserved pending receipt and review of required fish accumulation study.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

Date Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	A	No	-	Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A	Yes	00112990	No	
81-3 - Acute Inhalation Toxicity - Rat	TGAI	A	No	-	Yes	9 Months
81-7 - Delayed Neurotoxicity - Hen	TGAI	A	No	-	No/1	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding:	TGAI					
- Rodent, and		A	Yes	00037582	No/2	
- Non-rodent (Dog)		A	No	-	Yes/3	
82-2 - 21-Day Dermal - Rabbit	TGAI	A	No	-	Yes	12 Months
82-5 - 90-Day Neurotoxicity:	TGAI					
- Hen		A	No	-	No/1	
-Mammal		A	No	-	No/1	

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
CHRONIC TESTING:						
83-1 - Chronic Toxicity - 2 species:	TGAI					
- Rodent, and		A	Yes	00037582 00113001	No	
- Non-rodent (Dog)		A	Partial	00037583	Yes/4	50 Months
83-2 - Oncogenicity - 2 species:	TGAI					
- Rat (preferred), and		A	Yes	00037582 00113001	No	
- Mouse (preferred)		A	Partial	00037581	Yes/5	50 Months
83-3 - Teratogenicity - 2 species:	TGAI					
- Rat		A	Yes	00072693	No	
- Rabbit		A	Yes	00079319	No	
83-4 - Reproduction - Rat 2-generation	TGAI	A	No	-	Yes	39 Months
MUTAGENICITY TESTING						
84-2 - Gene Mutation (Ames Test)	TGAI	A	No	-	Yes	9 Months
84-2 - Structural Chromosomal Aberration	TGAI	A	No	-	Yes	12 Months
84-4 - Other Genotoxic Effects	TGAI	A	No	-	Yes	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA		No	-	Yes	24 Months

1/ Because fenbutatin-oxide is not an organophosphate chemical and available data indicate that there are no neurotoxicological problems associated with this chemical, data are not needed at this time.

2/ There are adequate chronic toxicity data to satisfy this data requirement.

3/ These studies will not be necessary if adeuquate chronic toxicity studies are submitted.

4/ This study may be upgraded to an acceptable level with the submission of the following data:

a. The composition of the test material used in this dog study and the composition of the technical material currently marketed and registered product.

b. An explanation for carrying out this experiment in two time periods, six weeks apart.

4/ continued-

c. Raw data and summary tables on urinalysis.

d. Individual animal data on macroscopic and microscopic lesions with the data presented in parallel columns on the same page for the same animal.

e. Listing of all tissues examined grossly and micrscopically with a description of all gross lesions observed and/ or examined.

f. Summary tables for the incidence of macroscopic and microscopic lesions.

If this information is no longer available a new study must be submitted.

5/ This study may be upgraded with the submission of the following data:

a. Analysis of feed administered to treated animals for test material content.

b. Measurement of food consumption.

c. Necropsy information.

d. Adequate number of tissues subjected to microscopic examination.

e. Summary of incidence table of neoplastic and non-neoplastic pathology based upon number of tissues examined by sex and dose.

f. Identification of tissues examined histologiclally and organ weight.

If this information is no longer available, a new study must be submitted.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A	No	-	Yes	27 Months
132-1 - Soil Dissipation	TEP	A	No	-	No/1	
§158.142 Spray Drift						
201-1 - Droplet Size Spectrum	TEP	N/A	No	-	No/2	
201-1 - Drift Field Evaluation	TEP	N/A	No	-	No/2	

1/ Soil dissipation data not required if acceptable foliar data are submitted.
2/ Because this chemical is applied by ground application, only, there are no spray drift requirements.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Acute Avian Oral Toxicity	TGAI	A,B/1	Yes	00113073	No	
71-2 - Avian Subacute Dietary Toxicity	TGAI					
- Upland Game Bird, and		A,B/1	No	-	Yes	9 Months
- Waterfowl		A,B	Yes	00113074	No	
71-3 - Wild Mammal Toxicity	TGAI	A,B	No	-	No/2	
71-4 - Avian Reproduction	TGAI					
- Upland Game Bird, and		A,B	No	-	Yes/3	24 Months
- Waterfowl		A,B	No	-	Yes/3	24 Months
71-5 - Simulated Field Testing	TEP					
- Mammals, and		A,B	No	-	Reserved/4	
- Birds		A,B	No	-	Reserved/4	
- Actual Field Testing	TEP					
- Mammals, and		A,B	No	-	Reserved/4	
- Birds		A,B	No	-	Reserved/4	

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish Toxicity	TGAI					
- Coldwater Fish Species, and		A,B/1	Yes	00113075	No	
-Coldwater Fish Species	TEP (4lb/gal FC)	A	No	-	Yes/5	9 Months
- Warmwater Fish Species	TGAI	A,B	Yes	00113076	No	
- Warmwater Fish Species	TEP (4lb/gal FC)	A	No	-	Yes/5	9 Months
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,B/1	No	-	Yes	9 Months
	TEP (4lb/gal FC)	A	No	-	Reserved/5	
72-3 - Acute Toxicity to Estuarine and Marine Organisms/6	TGAI					
- Fish		A,B	No	-	Yes	12 Months
- Mollusk		A,B	No	-	Yes	12 Months
- Shrimp		A,B	No	-	Yes	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
- Acute Toxicity to Estuarine and Marine Organisms/6	TEP (4lb/gal FC)					
- Fish		A	No	-	Reserved/7	
- Mollusk		A	No	-	Reserved/7	
- Shrimp		A	No	-	Reserved/7	
72-4 - Fish Early Life Stage,	TGAI					
- Freshwater	TGAI	A,B	No	-	Yes/8	15 Months
- Estuarine	TGAI	A,B	No	-	Reserved/9	
and						
- Aquatic Invertebrate Life-Cycle						
- Freshwater	TGAI	A,B	No	-	Yes/8	15 Months
-Estuarine	TGAI	A,B	No	-	Reserved/9	

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
72-5 - Fish - Life-Cycle	TGAI	A,B	No	-	Reserved/10	
72-6 - Aquatic Organism Accumulation	TGAI, PAI OR Degradation	A,B	No	-	Yes	12 Months
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	A	No	-	Yes/11	15 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

§158.145 Wildlife and Aquatic Organisms - Continued

1/ These data are required in order to support the manufacturing use product.
2/ Acute toxicity data indicate that this study is not required.
3/ Because the use directions for this product indicate the need for repeat applications, these data are required.
4/ This requirement is reserved pending receipt for avian reproduction data and additional environmental fate data.
5/ This data requirement is required to support the citrus use.
6/ This data requirement is required to support the citrus use. (Citrus is grown in coastal counties in excess of 300,000 acres).
7/ Reserved pending the outcome of acute studies on the tehcnical material and monitoring data.
8/ This data requirement is required to support the orchard uses.
9/ This requirement is reserved pending the outcome of the chronic studies on freshwater organisms, and on acute estuarine organism testing on the technical and the monitoring data.
10/ This requirement is reserved pending the outcome of required chronic studies on freshwater and estuarine organisms and monitoring data.
11/ Aquatic residue monitoring studies on fenbutatin-oxide and its major metabolities are required to determine exposure levels (acute and chronic) in Florida citrus groves and adjacent waters. Monitoring of these sites is necessary due to the demonstrated aquatic toxicity and persistnace of fenbutatin-oxide. Based on use information, pesticide history and topography, you must develop an acceptable protocol to sample a representative number of citrus use sites (at least 5). A protocol must be submitted within 3 months of receipt of this guidance document. Monitoring efforts should focus on citrus production sites with a history of fenbutatin-oxide use and having extensive adjacent water bodies and canals (freshwater and estuarine). Residue monitoring studies must incorporate the following design characteristics:

A. Sampling shall include grove soil and adjacent waters: water column, sediment, benthic invertebrates and endemic fish (particularly bottom feeders).
B. Analytical methodology used to measure residuses must be described.
C. Sampling stations must be described on U.S.G.S. topographicbathymetric 7.5 minute series maps.
D. Soil and sediment characteristics of the sites being monitored must be specified.
E. Samples should be taken before, during and following applications of the pesticide and should include control sites.
F. Sampling should be done at regular intervals for a long enough period of time to account for such things as seasonal and use variations.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.150 Plant Protection						
121-1 - TARGET AREA PHYTOTOXICITY	EP		1/			
NONTARGET AREA PHYTOTOXICITY						
TIER I						
122-1 - Seed Germination/ Seedling Emergence	TGAI		1/			
122-1 - Vegetative Vigor	TGAI		1/			
122-2 - Aquatic Plant Growth	TGAI		1/			
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI		1/			
123-1 - Vegetative Vigor	TGAI		1/			
123-2 - Aquatic Plant Growth	TGAI		1/			
TIER III						
124-1 - Terrestrial Field	TEP		1/			
124-2 - Aquatic Field	TEP		1/			

1/ These data are not required in accordance with §158.150.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.155 Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honey bee acute contact toxicity	TGAI	A,B	Yes	00036935	No	
141-2 - Honey bee - toxicity of residues on foliage	TEP	A,B	Yes	00088398	No	
141-4 - Honey bee subacute feeding study	(Reserved)1/					
141-5 - Field testing for pollinators	TEP	A,B	No		No/2	
NONTARGET INSECT TESTING - AQUATIC INSECTS:						
142-1 - Acute toxicity to aquatic insects	(Reserved)3/					
142-1 - Aquatic insect life-cycle study	(Reserved)3/					
142-3 - Simulated or actual field testing for aquatic insects	(Reserved)3/					
143-1 thru 143-3 - **NONTARGET INSECT TESTING - PREDATORS AND PARASITES**	(Reserved)3/					

TABLE A
GENERIC DATA REQUIREMENTS FOR FENBUTATIN-OXIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.155 Nontarget Insect						

1/ Reserved pending development of methodology.

2/ As data from the acute and residual test indicate low toxicity, no further testing is required.

3/ Reserved pending Agency decision as to whether the data requirement should be established.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FENBUTATIN-OXIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data? 1/	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	No	-	Yes 2/	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	No	-	Yes 2/	6 Months
61-3 - Discussion of Formation of Impurities	MP	All	No	-	Yes 2/	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	All	No	-	Yes 2/	12 Months
62-2 - Certification of Limits	MP	All	No	-	Yes 2/	12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	All	No	-	Yes 2/	12 Months
Physical and Chemical Characteristics						
63-2 - Color	MP	All	No	-	Yes 2/	6 Months
63-3 - Physical State	MP	All	No	-	Yes 2/	6 Months
63-4 - Odor	MP	All	No	-	Yes 2/	6 Months

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FENBUTATIN-OXIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data? 1/	Bibliographic Citation	Must Additional Data be Submitted? 2/	Time Frame for Submission
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	MP	All	No	-	Yes 2/	7 Months
63-12 - pH	MP	All	No	-	Yes 2/	7 Months
63-14 - Oxidizing or Reducing Action	MP	All	No	-	Yes 2/	7 Months
63-15 - Flammability	MP	All	No	-	Yes 2/	7 Months
63-16 - Explodability	MP	All	No	-	Yes 2/	7 Months
63-17 - Storage Stability	MP	All	No	-	Yes 2/	16 Months
63-18 - Viscosity	MP	All	No	-	Yes 2/	7 Months
63-19 - Miscibility	MP	All	No	-	Yes 2/	7 Months
63-20 - Corrosion Characteristics	MP	All	No	-	Yes 2/	7 Months

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1/ Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each manufacturing use product. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

2/ Product Specific data are required for the following formulation: EPA REG. NO. 201-367.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FENBUTATIN-OXIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted? 1/	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral Toxicity - Rat	MP	All	No	-	Yes 1/	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	MP	All	Yes	00112990	No	
81-3 - Acute Inhalation Toxicity - Rat	MP	All	No	-	Yes 1/	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	All	Yes	00112990	No	
81-5 - Primary Dermal Irritation - Rabbit	MP	All	Yes	00112990	No	
81-6 - Dermal Sensitization - Guinea Pig	MP	All	Yes	00112990	No	

1/ Product Specific data are required for the following formulation: EPA REG. NO. 201-367.

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

SUMMARY-2

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-8

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

~~cant obtained the data from another firm (identify); applicant copied data from a publication; applicant obtained a copy of the data from EPA).~~

~~(d) The applicant shall submit with his application a statement that EPA, in its evaluation of the properties, efficacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:~~

~~(1) The data the applicant has submitted to EPA under paragraph (b) of this section;~~

~~(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and~~

~~(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.~~

~~(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:~~

~~(1) A notification of the applicant's intent to apply for registration, including the proposed product name;~~

~~(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);~~

~~(3) An identification of the item(s) of data to which the offer applies;~~

~~(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and~~

~~(5) The applicant's name, address, and telephone number.~~

~~(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.9–5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on the Administrator's consideration of) the following data:~~

~~(1) All data submitted or specifically cited by the applicant in support of the registration; and~~

~~(2) Each other item of data in the Agency's files which:~~

~~(i) Concerns the properties or effects of any such active ingredient; and~~

~~(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.~~

(Secs. 3, 6, and 25 of FIFRA, as amended, 7 U.S.C. 136 *et seq.*)

[44 FR 27953, May 11, 1979]

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(continued)

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an addi-

(c) *Name and address of producer, registrant, or person for whom produced.* An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label

(continued)

allel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any

inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD₅₀	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC₅₀	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2. thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD₅₀	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practi-

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cal treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD50 of

100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which ac-

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in

(continued)

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(3) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

~~§ 162.11 Criteria for determinations of unreasonable adverse effects.~~

~~(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing*—(1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty-five (45) days from the date such notice is sent to submit evidence in rebuttal of the presumption; provided, however, that for good cause shown the Administrator may grant an additional sixty~~

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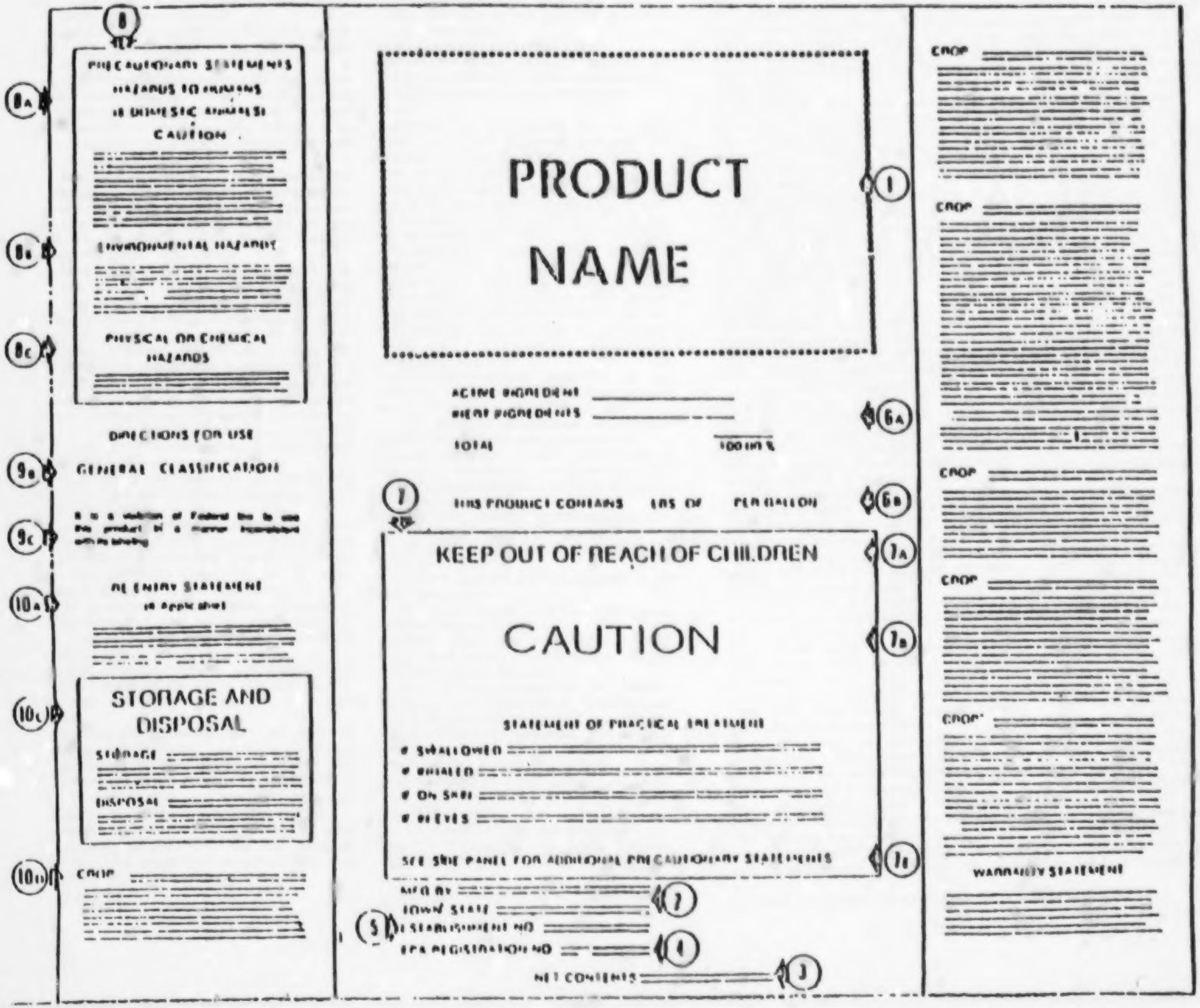
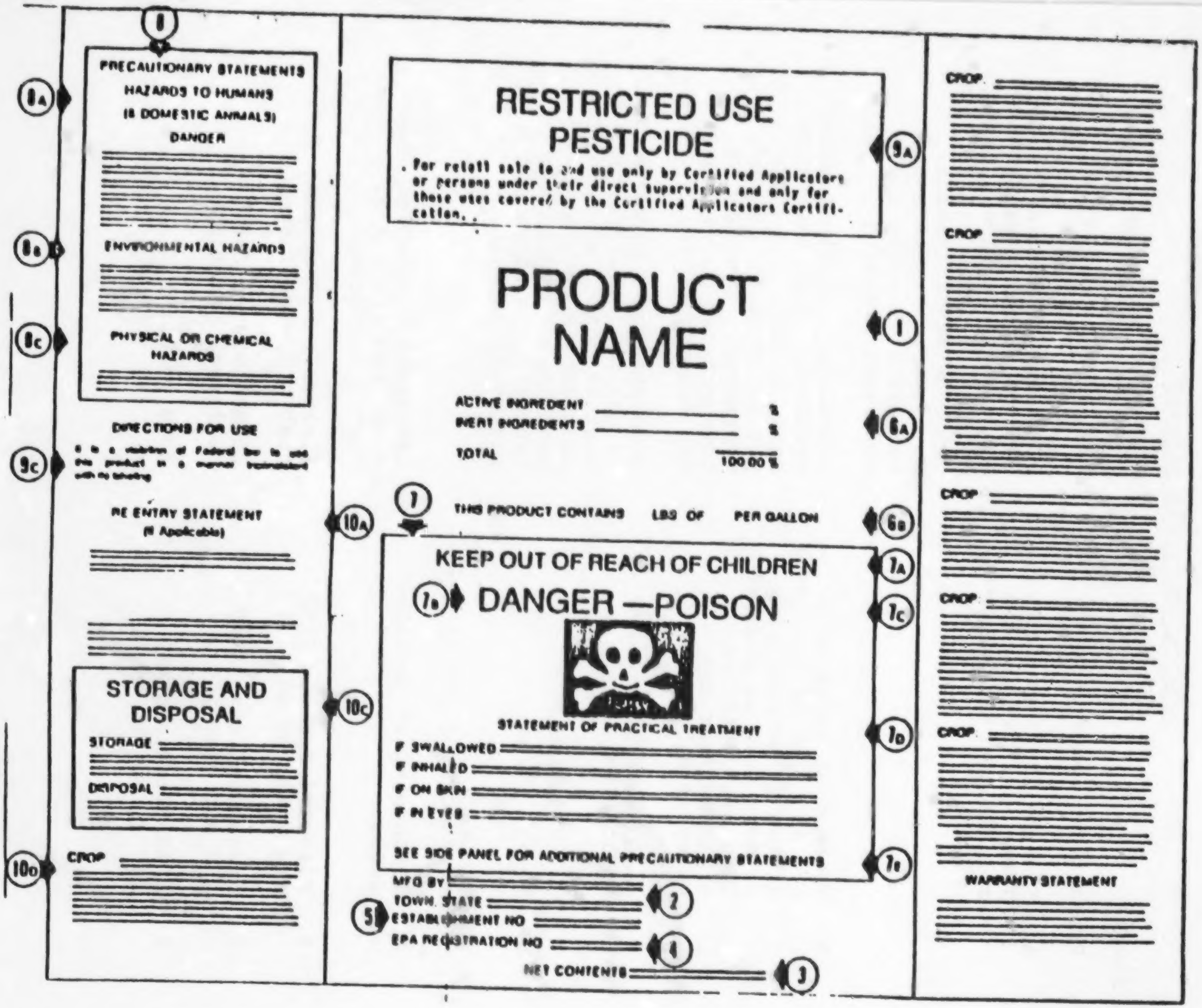

8
8A
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
CAUTION
8B
ENVIRONMENTAL HAZARDS
8C
PHYSICAL OR CHEMICAL HAZARDS
DIRECTIONS FOR USE
9A
GENERAL CLASSIFICATION
9C
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
10A
RE-ENTRY STATEMENT
(If Applicable)
10C
STORAGE AND DISPOSAL
STORAGE
DISPOSAL
10D
CROP
PRODUCT NAME
1
ACTIVE INGREDIENT
INERT INGREDIENTS
TOTAL
100.00%
6A
7
THIS PRODUCT CONTAINS LBS OF PER GALLON
6B
KEEP OUT OF REACH OF CHILDREN
7A
CAUTION
7B
STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
7C
MFD BY
TOWN, STATE
2
ESTABLISHMENT NO
5
EPA REGISTRATION NO
4
NET CONTENTS
3
CROP
CROP
CROP
CROP
CROP
WARRANTY STATEMENT


8
8A
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER
8B
ENVIRONMENTAL HAZARDS
8C
PHYSICAL OR CHEMICAL HAZARDS
DIRECTIONS FOR USE
9C
It is a violation of Federal law to use this product in a manner inconsistent with its labeling
RE ENTRY STATEMENT
(If Applicable)
10A
10C
STORAGE AND DISPOSAL
STORAGE
DISPOSAL
10D
CROP
RESTRICTED USE PESTICIDE
For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicators Certification.
9A
PRODUCT NAME
1
ACTIVE INGREDIENT %
INERT INGREDIENTS %
TOTAL 100.00 %
6A
7
THIS PRODUCT CONTAINS LBS OF PER GALLON
6B
KEEP OUT OF REACH OF CHILDREN
7A
7B
DANGER —POISON
7C
STATEMENT OF PRACTICAL TREATMENT
7D
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
7E
MFG BY
TOWN, STATE
2
5
ESTABLISHMENT NO
EPA REGISTRATION NO
4
NET CONTENTS
3
CROP
CROP
CROP
CROP
CROP
WARRANTY STATEMENT

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20'F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130'F may cause bursting.
B. Flashpoint above 20'F and not over 80'F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130'F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130'F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20'F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20'F and not over 80'F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80'F and not over 150'F.	Do not use or store near heat and open flame.
D. Flashpoint above 150'F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.
2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.
3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.
4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.
5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.
6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

PESTICIDE ACTIVE INGREDIENTS THAT ARE ACUTE HAZARDOUS WASTES

I. PESTICIDES ON THE "E" LIST (with RCRA # and CAS
[40 CFR 261.33(e)]

Acrolein	P003	107-13-1
Aldicarb	P070	116-06-3
Aldrin	P004	309-00-2
Allyl alcohol	P005	107-18-6
Aluminum phosphide	P006	1302-45-0
4-Aminopyridine (Avitrol)	P008	504-24-5
Arsenic acid	P010	7778-39-4
Arsenic pentoxide	P011	1303-28-2
Arsenic trioxide	P012	1327-53-3
Calcium cyanide	P021	592-01-8
Carbon disulfide	P022	75-15-0
p-Chloroaniline	P024	106-47-8
Cyanides (soluble cyanide salts not otherwise specified)	P030	
Cyanogen chloride	P031	506-77-4
Dieldrin	P037	60-57-1
O,O-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate (disulfoton)	P039	298-04-4
O,O-Diethyl O-pyrazinyl phosphorothioate (Zinophos\)	P040	297-97-2
Dimethoate	P044	60-51-5
O,O-Dimethyl O-p-nitrophenyl phosphorothioate (methyl parathion)	P071	298-00-0
4,6-Dinitro-o-cresol and salts	P047	534-52-1
4,6-Dinitro-o-cyclohexylphenol	P034	131-89-5
Dinoseb	P020	88-85-7
Endosulfan	P050	115-29-7
Endothall	P088	129-67-9
Endrin	P051	72-20-8
Famphur	P097	52-85-7
Fluoroacetamide	P057	640-19-7
Heptachlor	P059	76-48-8
Hexachlorohexahydro-exo,exo-dimethanonaphthalene (Isodrin)	P069	465-73-6
Hydrocyanic acid	P063	74-90-8
Methomyl	P066	16752-77-5
alpha-Naphthylthiourea (ANTU)	P072	86-88-41
Nicotine and salts	P075	54-11-5
Octamethylpyrophosphoramide (OMPA, schradan)	P085	152-16-9
Parathion	P089	56-38-2
Phenylmercuric acetate (PMA)	P092	62-38-4
Phorate	P094	298-02-2
Potassium cyanide	P098	151-50-8
Propargyl alcohol	P102	107-19-7
Sodium azide	P105	26628-22-8
Sodium cyanide	P106	143-33-9
Sodium fluoroacetate	P058	62-74-8

Strychnine and salts	P108	57-24-9 60-41-3
O,O,O,O-Tetraethyl dithiopyrophosphate (sulfotepp)	P109	3689-24-5
Tetraethyl pyrophosphate	P111	107-49-3
Thallium sulfate	P115	7446-18-6
Thiofanox	P045	39196-18-4
Toxaphene	P123	8001-35-2
Warfarin (>0.3%)	P001	81-81-2
Zinc phosphide (>10%)	P122	1314-84-7

50 ACTIVES

II. PESTICIDES DERIVED FROM TRI-, TETRA-, AND PENTACHLOROPHENOLS [40 CFR 261.31]

2-Chloroethyl 2-(2,4,6-trichlorophenoxy) ethyl ether	F027	5324-22-1
Dehydroabietylammonium pentachlorophenoxide	F027	35109-57-0
Erbon	F027	136-25-4
O-ethyl O-(2,4,5-trichlorophenyl) ethylphosphonothioate	F027	327-98-0
2,2'-Methylenebis (3,4,6-trichlorophenol) (Hexachlorophene)	F027	70-30-4
--Potassium salt of	F027	67923-62-0
--Sodium salt of	F027	3247-34-5
--Disodium salt of	F027	5736-15-2
Pentachlorophenol	F027	87-86-5
--Potassium salt of	F027	7778-73-6
--Sodium salt of	F027	131-52-2
--Zinc salt of	F027	2917-32-0
--Zinc salt of N-alkyl (C_{16}-C_{18})-1,3-propanediamine	F027	
--Pentachlorophenyl laurate	F027	3772-94-9
Potassium trichlorophenate (2,4,6)	F027	2591-21-1
Potassium trichlorophenate (2,4,5)	F027	35471-43-3
Silvex	F027	93-72-1
--2-Butoxyethyl ester	F027	19398-13-1
--Butoxypolypropoxypropyl ester	F027	53404-07-2
--Butoxypropyl ester	F027	25537-26-2
--Diethanolamine salt	F027	51170-59-3
--Diisopropanolamine salt	F027	53404-09-4
--Dimethylamine salt	F027	55617-85-1
--Dipropylene glycol isobutyl ether ester	F027	53535-26-5
--Ethanolamine salt	F027	7374-47-2
--2-Ethylhexyl ester	F027	53404-76-5
--Isooctyl ester	F027	53404-14-1

--Isopropanolamine salt	F027	53404-13-0
--Monohydroxylaluminum salt	F027	69622-82-8
--Polypropoxypropyl ester	F027	83562-66-7
--Potassium salt	F027	2818-16-8
--Propylene glycol isobutyl ether ester	F027	53466-84-5
--Sodium salt	F027	37913-89-6
--Triethanolamine salt	F027	17369-89-0
--Triethylamine salt	F027	53404-74-3
--Triisopropanolamine salt	F027	53404-75-4
--Tripropylene glycol isobutyl ether ester	F027	53535-30-1
Sodium 2-(2,4,5-trichlorophenoxy) ethyl sulfate	F027	3570-61-4
Tetrachlorophenols	F027	25167-83-3
--Alkylamine*amine salt (as in fatty acids of coconut oil)	F027	
--Potassium salt	F027	53535-27-6
--Sodium salt	F027	25567-55-9
2,4,5-Trichlorophenol	F027	95-95-4
2,4,6-Trichlorophenol	F027	88-06-2
2,4,5-Trichlorophenol salt of 2,6-bis[(dimethylamino)methyl] cyclohexanone	F027	53404-83-4
2,4,5-Trichlorophenol, sodium salt	F027	136-32-3
2,4,6-Trichlorophenol, sodium salt	F027	3784-03-0
2,4,5-Trichlorophenoxyacetic acid	F027	93-79-8
--Alkyl C-12 amine salt	F027	53404-84-5
--Alkyl C-13 amine salt	F027	53404-85-6
--Alkyl C-14 amine salt	F027	53535-37-8
--N,N-diethylethanolamine salt	F027	53404-86-7
--Dimethylamine salt	F027	6369-97-7
--N,N-dimethyllinoleylamine salt	F027	53404-88-9
--N,N-dimethyloleylamine salt	F027	53404-89-0
--N-oleyl-1,3-propylene diamine salt	F027	53404-87-8
--Sodium salt	F027	13560-99-1
--Triethanolamine salt	F027	3813-14-7
--Triethylamine salt	F027	2008-46-0
--Alkyl (C3H7 - C7H9) ester	F027	
--Amyl ester	F027	120-39-8
--Butoxyethoxypropyl ester	F027	1928-58-1
--2-Butoxyethyl ester	F027	2545-59-7
--Butoxypropyl ester	F027	1928-48-9
--Butyl ester	F027	93-79-8
--Dipropylene glycol isobutyl ether ester	F027	53535-31-2
--2-Ethylhexyl ester	F027	1928-47-8
--Isobutyl ester	F027	4938-72-1

--Isopropyl ester	F027	93-78-7
--Propylene glycol isobutyl ether ester	F027	53466-86-7
--Tripropylene glycol isobutyl ether ester	F027	53535-32-3
4-(2,4,5-Trichlorophenoxy)butyric acid [2,4,5-TB]	F027	93-80-1
2-(2,4,5-Trichlorophenoxy)ethyl hydrogen sulfate [2,4,5-TES]	F027	69633-04-1
1,4',5'-Trichloro-2'-(2,4,5-trichlorophenoxy) methanesulfonanilide [Edolan U]	F027	69462-14-2

PESTICIDES THAT ARE TOXIC HAZARDOUS WASTES

PESTICIDES ON THE "F" LIST [40 CFR 261.33(f)] (with	RCRA #, and	CAS #
Acetone	U002	67-64-1
Acrylonitrile*	U009	107-13-1
Amitrole	U011	61-82-5
Benzene*	U019	71-43-2
Bis(2-ethylhexyl)phthalate	U028	117-81-7
Cacodylic acid	U136	75-60-5
Carbon tetrachloride*	U211	56-23-5
Chloral (hydrate) (chloroacetaldehyde)	U034	302-17-0
Chlordane, technical*	U036	57-74-9
Chlorobenzene*	U037	108-90-7
4-Chloro-m-cresol	U039	59-50-7
Chloroform*	U044	67-66-3
o-Chlorophenol	U048	95-57-8
Creosote	U051	8021-39-4
Cresylic acid (cresols)*	U052	1319-77-3
Cyclohexane	U056	110-82-7
Cyclohexanone	U057	108-94-1
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one (Kepone, chlordecone)	U142	143-50-0
1,2-Dibromo-3-chloropropane (DBCP)	U066	96-12-8
Dibutyl phthalate	U069	84-74-2
S-2,3-(Dichloroallyl diisopropylthiocarbamate) (diallate,Avadex)	U062	2303-16-4
o-Dichlorobenzene*	U070	95-50-1
p-Dichlorobenzene*	U072	106-46-7
Dichlorodifluoromethane (Freon 12\)	U075	75-71-8
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide, Kerb\)	U192	23950-58-5
Dichloro diphenyl dichloroethane (DDD)	U060	72-54-8
Dichloro diphenyl trichloroethane (DDT)	U061	50-29-3
Dichloroethyl ether	U025	1191-17-9
2,4-Dichlorophenoxyacetic, salts and esters (2,4-D)*	U240	94-75-7
1,2-Dichloropropane	U083	8003-19-8
1,3-Dichloropropene (Telone)	U084	542-75-6
Dimethyl phthalate	U102	131-11-3
Epichlorohydrin (1-chloro-2,3-epoxypropane)	U041	106-89-8
Ethyl acetate	U112	141-78-6
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)	U038	510-15-6

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*Proposed for deletion by TCLP proposal

Ethylene dibromide (EDB)	U067	106-93-4
Ethylene dichloride*	U077	107-06-2
Ethylene oxide	U115	75-21-8
Formaldehyde	U122	50-00-0
Furfural	U125	98-01-1
Hexachlorobenzene*	U127	118-74-1
Hexachlorocyclopentadiene	U130	77-47-4
Hexachloroethane*	U131	67-72-1
Hydrofluoric acid	U134	7664-39-3
Isobutyl alcohol*	U140	78-83-1
Lead acetate	U144	301-04-2
Lindane*	U129	58-89-9
Maleic hydrazide	U148	123-33-1
Mercury	U151	7439-97-6
Methoxychlor*	U247	72-43-5
Methyl alcohol (methanol)	U154	67-56-1
Methyl bromide	U029	74-83-9
Methyl chloride	U045	74-87-3
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene) [acute waste per 261.31]	U132	70-30-4
Methylene chloride*	U080	75-09-2
Methyl ethyl ketone*	U159	78-93-3
4-Methyl-2-pentanone (methyl isobutyl ketone)	U161	108-[illegible]0-1
Naphthalene	U165	91-20-3
Nitrobenzene*	U169	98-95-3
p-Nitrophenol	U170	100-02-7
Pentachloroethane	U184	76-01-7
Pentachloronitrobenzene (PCNB)	U185	82-68-8
Pentachlorophenol* [acute waste per 261.31]	U242	87-86-5
Phenol*	U188	108-95-2
Pyridine*	U196	110-86-1
Resorcinol	U201	108-46-3
Safrole	U203	94-59-7
Selenium disulfide	U205	7488-56-4
Silvex [acute waste per 261.31]	U233	93-72-1
1,1,2,2-Tetrachloroethane*	U209	79-34-5
Tetrachloroethylene*	U210	127-18-4
2,3,4,6-Tetrachlorophenol* [acute waste per 261.31]	U212	
Thiram	U244	137-26-8
Toluene*	U220	108-88-3
1,1,1-Trichloroethane* (methyl chloroform)	U226	71-55-6
Trichloroethylene*	U228	79-01-6
Trichloromonofluoromethane (Freon 11\)	U121	75-69-4
2,4,5-Trichlorophenol* [acute waste per 261.31]	U230	95-95-4
2,4,6-Trichlorophenol* [acute waste per 261.31]	U231	88-06-2

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)* [acute waste per 261.31]	U232	93-76-5
Warfarin (<0.3%)	U248	81-81-2
Xylene	U239	1330-20-7
Zinc phosphide (<10%)	U249	1314-84-7

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FINAL
SAI / SAI
104601

HEXAKIS(2-METHYL-2-PHENYLPROPYL)DISTANNOXANE

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c104601

HEXAKIS(2-METHYL-2-PHENYLPROPYL)DISTANNOXANE*

TYPE PESTICIDE: Acaricide

FORMULATIONS:
Tech (97%)
WP (50%) (water soluble package)
FlC (4 lb/gal)

GENERAL WARNINGS AND LIMITATIONS: Do not get into eyes, on skin, or on clothing. Wear suitable eye protection, such as goggles or safety glasses with side shields or their equivalent, when pouring liquid product from container or handling wettable powder products. Avoid handling inner water soluble bag of wettable powder products as moisture will cause breakage. During commercial application or other prolonged exposure, use goggles and face mask. Wear clean protective clothing that covers the body well. Do not graze or feed animals on cover crops grown in treated areas. Avoid contamination of food, feedstuffs and domestic water supplies.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Keep out of lakes, ponds and streams. Do not contaminate water by cleaning of equipment or disposal of wastes.

USE DIRECTIONS: Apply hexakis only by ground equipment. Hexakis may be applied when honeybees and other beneficials are present.

REENTRY STATEMENTS: Do not apply hexakis in such a manner as to directly or through drift expose workers or other persons. The area being treated must be vacated by unprotected persons. Do not enter treated areas without protective clothing until sprays have dried. California and Texas have a 1 day reentry period.

Commodity Tolerances (other than those listed in the text):

Cattle, fat	0.5 ppm
Cattle, meat	0.5 ppm
Cattle, mbyp	0.5 ppm
Cucumbers	4.0 ppm
Eggs	0.1 ppm
Goats, fat	0.5 ppm
Goats, meat	0.5 ppm
Goats, mbyp	0.5 ppm
Hogs, fat	0.5 ppm
Hogs, meat	0.5 ppm
Hogs, mbyp	0.5 ppm
Horses, fat	0.5 ppm
Horses, meat	0.5 ppm
Horses, mbyp	0.5 ppm
Milk, fat	0.1 ppm
Poultry, fat	0.1 ppm
Poultry, meat	0.1 ppm

*hexakis (beta,beta-dimethylphenethyl)distannoxane
Vendex
Fenbutatin-oxide

GENERAL WARNINGS AND LIMITATIONS (continued)

Poultry, mbyp	0.1 ppm
Raspberry	10 ppm (proposed 6/11/86)
Sheep, fat	0.5 ppm
Sheep, meat	0.5 ppm
Sheep, mbyp	0.5 ppm

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	TERRESTRIAL FOOD CROP		
	(Agricultural Crops)		
03001AA	Almond		0.5 ppm (almonds) 80 ppm (hulls) 14 day preharvest interval through 1.25 pounds per acre. Do not apply more than 2 times per season.
ILAVASA ILAVBAA ILAVBQA ILAVBEA	European red mite Pacific spider mite Pecan leaf scorch mite (Pecan spider mite/Hickory spider mite) Twospotted spider mite	0.125-0.25 lb/100 gal [up to 500 gal/A] (50% WP) 000201-00369 (4 lb/gal FlC) 000201-00412	Dilute foliar application. Apply when mites first appear and repeat as necessary to maintain control.
		or	
		0.5-1.25 lb/A (50% WP) (4 lb/gal FlC)	Concentrate foliar application. Apply when mites first appear and repeat as necessary to maintain control.

HEXAKIS(2-METHYL-2-PHENYLPROPYL)DISTANNOXANE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/04001AA	Apple		15 ppm (apples) 75 ppm (dried apple pomace) 14 day preharvest interval through 1.5 pounds per acre. Do not apply more than 4 times per season including a prebloom spray; apply no more than 3 times between petal fall and harvest.
ILAJAKA	Apple rust mite	0.125-0.25 lb/100 gal [up to 600 gal/A] (50% WP) 000201-00369 (4 lb/gal FlC) 000201-00412 or	Dilute foliar application. Apply when mites first appear and repeat as necessary to maintain control.
ILAVASA	European red mite		
ILAVAYA	McDaniel spider mite		
ILAVBEA	Twospotted spider mite		
ILAVAEA	Yellow spider mite (Carpini spider mite)		
		0.5-1.5 lb/A (50% WP) (4 lb/gal FlC)	Concentrate foliar application. Apply when mites first appear and repeat as necessary to maintain control.
/05002AA	Cherry		6 ppm (cherries, sweet and sour) 14 day preharvest interval through 1.5 pounds per acre. Do not apply more than 2 times per season.
ILAJBEA	Cherry rust mites	0.125-0.25 lb/100 gal [up to 600 gal/A] (50% WP) 000201-00369 (4 lb/gal FlC) 000201-00412 or	Dilute foliar application. Apply when mites first appear and repeat as necessary to maintain control.
ILAVASA	European red mite		
ILAVAYA	McDaniel spider mite		
		0.75-1.5 lb/A (50% WP) (4 lb/gal FlC)	Concentrate foliar application. Apply when mites first appear and repeat as necessary to maintain control.

HEXAKIS(2-METHYL-2-PHENYLPROPYL)DISTANNOXANE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/02000AA	Citrus Fruits		20 ppm (citrus fruits) 35 ppm (dried citrus pulp) 7 day preharvest interval through 4 pounds per acre. Do not apply more than 4 sprays in any 12 month period.
ILAVARA ILAJBCA ILAVAKA ILAVBEA ILAVAJA	Citrus red mite Citrus rust mite Texas citrus mite Twospotted spider mite Yuma spider mite	0.125-0.25 lb/100 gal [up to 1,600 gal/A] (50% WP) 000201-00369 (4 lb/gal FlC) 000201-00412 or	Dilute foliar application. Apply when mites first appear and repeat as necessary to maintain control.
		1.0-2.0 lb/A (50% WP) (4 lb/gal FlC)	Concentrate foliar application. Apply when mites first appear and repeat as necessary to maintain control.
/11001AA	Eggplant		6 ppm 3 day preharvest interval through 2 pounds per acre. Do not exceed 6 applications per season with a total of no more than 6 pounds active ingredient per acre per year. Use limited to areas other than CA.
ILAVCJA ILAVBEA	Glover's mite Twospotted spider mite	1.0-2.0 lb/A (50% WP) 000201-00369 (4 lb/gal FlC) 000201-00412	Foliar application. Apply when mites appear. Repeat as necessary to maintain control. Thorough coverage for all leaf surfaces is required for best control. In Florida apply when needed or every 1 to 2 weeks.

EPA Index to Pesticide Chemicals

HEXAKIS(2-METHYL-2-PHENYLPROPYL)DISTANNOXANE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
01014AA	Grapes		5 ppm (grapes) 20 ppm (raisins or raisin waste) 100 ppm (dried grape pomace) 28 day preharvest interval through 1.25 pounds per acre. Do not apply more than 2 times per season.
ILAVARA ILAVBAA ILAVBEA	European red mite Pacific spider mite Twospotted spider mite	0.25-0.5 lb/100 gal [up to 250 gal/A] (50% WP) 000201-00369 (4 lb/gal FlC) 000201-00412 or	Dilute foliar application. Apply when mites first appear and repeat as necessary to maintain control but not within 21 days.
		0.5-1.25 lb/A (50% WP) (4 lb/gal FlC)	Concentrate foliar application. Apply when mites first appear. Repeat as necessary to maintain control but not within 21 days.
/06010AA	Papaya		2 ppm 7 day preharvest interval through 1 pound per acre. Do not apply more than once per month to bearing trees and not more than 9 times per season. Not registered for use in California.
ILATABA ILAVAWA ILAVARA ILAVAEA ILAVAKA	Broad mite Carmine spider mite Citrus red mite Red and black flat mite Texas citrus mite	0.125-0.25 lb/100 gal [up to 400 gal/A] (50% WP) 000201-00369	Dilute foliar application. Apply when mites first appear and repeat as necessary to maintain control.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
'05004AA '05005AA '05006AA	Peach Plum Prune		10 ppm (peaches, plums, prunes) 20 ppm (dried prunes) 14 day preharvest interval through 1 pound per acre. Do not apply more than 2 times per season.
ILBGABA	Bigbeaked plum mite	0.125-0.25 lb/100 gal [up to 400 gal/A] (50% WP) 000201-00369 (4 lb/gal FlC) 000201-00412 or	Dilute foliar application. Apply when mites first appear and repeat as necessary to maintain control.
ILAVARA	European red mite		
ILAVAYA	McDaniel spider mite		
ILAVBAA	Pacific spider mite		
ILAJAIA	Peach silver mite		
ILAJAJA	Plum rust mite (Plum nursery mite)		
ILAVBEA	Twospotted spider mite	0.5-1.0 lb/A (50% WP) (4 lb/gal FlC)	Concentrate foliar application. Apply when mites first appear and repeat as necessary to maintain control.
/04003AA	Pear		15 ppm 14 day preharvest interval through 1.5 pounds per acre. Do not apply more than 4 times per season including a prebloom spray; apply no more than 3 times between petal fall and harvest.
ILAVARA	European red mite	0.125-0.25 lb/100 gal [up to 600 gal/A] (50% WP) 000201-00369 (4 lb/gal FlC) 000201-00412 or	Dilute foliar application. Apply when mites first appear and repeat as necessary to maintain control.
ILAVAYA	McDaniel spider mite		
ILAJAOA	Pear rust mite		
ILAVBEA	Twospotted spider mite		
		0.5-1.5 lb/A (50% WP) (4 lb/gal FlC)	Concentrate foliar application. Apply when mites first appear and repeat as necessary to maintain control.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
3008AA	Pecan		0.5 ppm 14 day preharvest interval through 1.25 pounds per acre. Do not apply more than 2 times per season.
LAVBQA	Pecan leaf scorch mite (Pecan spider mite/Hickory mite)		Dilute foliar application. Concentrate foliar application.
		Refer to Pecan leaf scorch mite under Almond for use and limitation information.	
	Plum		See Peach cluster.
	Prune		See Peach cluster.
01016AA	Strawberry		10 ppm 1 day preharvest interval through 1 pound per acre. Do not apply more than 4 times per season.
ILAVBEA	Twospotted spider mite	0.375-0.5 lb/100 gal [150-200 gal/A] (50% WP) 000201-00369 (4 lb/gal FlC) 000201-00412 or	Dilute foliar application. Apply when mites first appear and repeat as necessary to maintain control. Adjust spray volume and nozzle placement to assure good coverage of top and underside of leaves.
		0.75-1.0 lb/A (50% WP) (4 lb/gal FlC)	Concentrate foliar application. Apply when mites first appear and repeat as necessary to maintain control. Adjust spray volume and nozzle placement to assure good coverage of top and underside of leaves.

HEXAKIS(2-METHYL-2-PHENYLPROPYL)DISTANNOXANE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
03009AA	Walnut		0.5 ppm 14 day preharvest interval through 1.25 pounds per acre. Do not apply more than 2 times per season.
ILAVASA ILAVBAA ILAVBEA	European red mite Pacific spider mite Twospotted spider mite		Dilute foliar application. Concentrate foliar application.

Refer to pests under Almond for use and limitation information.

TERRESTRIAL NONFOOD CROP

(Agricultural Crops)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/28085DA	Research Crops [including beans (snap, lima and wax), beets (table), corn (field and sweet), cucumbers, peas, peppers, spinach, squash (summer), tomatoes, and weed hosts of pathogens]		24(C) CA790076 (renewed 3/9/84) For use only at premises of Del Monte Corp., Alameda County. No part of treated plants may be used for food or feed. All applicable directions, restrictions and precautions on EPA registered label (201-369) are to be followed.
ILAAABA	Mites	2.25 g/gal (50% WP)	Foliar application to containerized plants using hand held wand. Spray to runoff.

(Ornamental Plants and Forest Trees)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/32000AA	Ornamental Plants		Do not add to oil spray solutions. Do not apply more than once every 28 days. Apply to foliage of chrysanthemums in the prebloom stage and to poinsettias in the prebract stage.
ILAVBNA ILAVAPA ILAVBEA	Oligonychus mites Spruce spider mite Twospotted spider mite	0.25-0.5 lb/ 100 gal (50% WP) 000201-00369 (4 lb/gal FlC) 000201-00412	Dilute foliar application. Apply when mites first appear and repeat as needed.

HEXAKIS(2-METHYL-2-PHENYLPROPYL)DISTANNOXANE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	GREENHOUSE NONFOOD CROP		
	(Agricultural Crops)		
./28083CA	Epcot Display Crops (not for consumption)		24(C) FL840002 For use only in "The Land", EPCOT Center, Lake Buena Visa, Florida. Crops (including resulting produce) not listed on the federal label must be destroyed following harvest and IN NO CASE SHOULD BE CONSUMED. All applicable directions, restrictions and precautions on the EPA-registered label are to be followed.
ILAJAKA	Apple rust mite	0.125-0.5 lb/ 100 gal or 0.5-2.0 lb/A (4 lb/gal F1C)	Dilute/concentrate foliar application.
ILBGABA	Bigbeaked plum mite		
ILAVARA	Citrus red mite		
ILAJBCA	Citrus rust mite		
ILAJBEA	Cherry rust mites		
ILAVASA	European red mite		
ILAVCJA	Glover's mite		
ILAVAYA	McDaniel spider mite		
ILAVBNA	Oligonychus mites		
ILAVBAA	Pacific spider mite		
ILAJAIA	Peach silver mite		
ILAJAOA	Pear rust mite		
ILAVBQA	Pecan leaf scorch mite (Pecan spider mite/Hickory spider mite)		
ILAJAJA	Plum rust mite (Plum nursery mite)		
ILAVAPA	Spruce spider mite		
ILAVAKA	Texas citrus mite		
ILAVBEA	Twospotted spider mite		
ILAVAEA	Yellow spider mite (Carpini spider mite)		
ILAVAJA	Yuma spider mite		

HEXAKIS(2-METHYL-2-PHENYLPROPYL)DISTANNOXANE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/28085DA	Research Crops [including beans (snap, lima and wax), beets (table), corn (field and sweet), cucumbers, peas, peppers, spinach, squash (summer), tomatoes, and weed hosts of pathogens]		24(C) CA790076 (renewed 3/9/84)
		Refer to TERRESTRIAL NON-FOOD CROP, (Agricultural Crops), Research Crop, for pests, use and limitation information.	
	(Ornamental Plants and Forest Trees)		
/32000AA	Ornamental Plants		Do not add oil spray to solutions. Do not apply more than once every 28 days. Apply to foliage of chrysanthemums in the prebloom stage and to poinsettias in the prebract stage.
ILAVBNA ILAVAPA ILAVBEA	Oligonychus mites Spruce spider mite Twospotted spider mite	0.25-0.5 lb/100 gal (50% WP) 000201-00369 (4 lb/gal FlC) 000201-00412	Dilute foliar application. Apply when mites first appear and repeat as needed.

HEXAKIS(2-METHYL-2-PHENYLPROPYL)DISTANNOXANE

Listing of Registered Pesticide Products by Formulation

097.0001 97% technical chemical
hexakis(2-methyl-2-phenylpropyl)distannoxane (104601)
000201-00367

050.0006 50% wettable powder
hexakis(2-methyl-2-phenylpropyl)distannoxane (104601)
000201-00369

204.0015 4 lb/gal flowable concentrate
hexakis(2-methyl-2-phenylpropyl)distannoxane (104601)
000201-00412

Intrastate Registrations

None

Special Local Need (24(c)) Registrations

(000201-00369):	CA78013400	CA79007600	CA80011600	FL79001800
	FL83002600	FL84002700	GA83000401	NY81000300
	OR78004100	TX83003400		
(000201-00412):	AR83001400	FL83002700	FL84000200	FL84002800
	GA83000402	PA80003300	TX83003300	

HEXAKIS (2-METHYL-2-PHENYLPROPYL)DISTANNOXANE

Auxiliary Documentation

000201-00369 - Jacket missing.

000201-00412 - The statement, "Do not use Vendex 4L on the following citrus: tangerines, tangelos" appearing on this label was deleted Oct. 17, 1985 in response to a request dated Aug. 12, 1985. The currently accepted label 11/27/85 was submitted for approval Sept. 23, 1985, i.e., before the agreement to delete the statement was approved.

24(C) 790076 renewed 3/9/84 does not take into account that this product is now marketed in water soluble bags.

24(C) FL840002 fails to list sites of application, pests controlled, dosages, and any other use directions. The only instructions it gives are to apply to Epcot Display Crops at the dosage rates listed on 000201-00412. As such I am indicating the full range of dosages, 0.125-0.5 pounds per 100 gallons water or 0.5-2.0 lb/A and am listing all the pests on 000201-00412. I believe that the registrant should be asked to list all crops grown at the Epcot Center and applicable pests and dosages.

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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00037581	Granville, G.C.; Simpson, B.J.; Doak, S.M.; et al. (1973) Toxicity Studies on the Pesticide SD 14114: An 18 Month Feeding Study in Mice: TLGR.0036.73. (Unpublished study received on unknown date under 4F1492; prepared by Shell Research, Ltd., submitted by Shell Chemical Co., Washington, D.C.; CDL:093941-H)
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